OPTN Pancreas Transplantation Committee
Meeting Summary
November 4, 2024
Conference Call

Dolamu Olaitan, MD, Chair
Ty Dunn, MD, MS, FACS, Vice Chair

Introduction

The OPTN Pancreas Transplantation Committee (the Committee) met via Cisco Webex teleconference on 11/04/24 to discuss the following agenda items:

1. Discussion: Facilitated Pancreas
2. Discussion: Winter 2025 Public Comment
3. Graft Failure Next Steps

The following is a summary of the Committee's discussions.

1. Discussion: Facilitated Pancreas

The Committee reviewed and refined recommendations on facilitated pancreas allocation, building upon discussions from the October in-person meeting.

Data summary:

Previous Committee recommendations for FP allocation:

- OPOs and the OPTN are permitted to make FP offers if no pancreas offer has been accepted **five hours** prior to the scheduled donor organ recovery
- Apply facilitated pancreas bypasses to candidates registered at transplant hospitals > **250NM** from the donor hospital
- Apply bypasses to **kidney-pancreas (KP) and pancreas** candidates
- Bypass all candidates at non-facilitated programs, **regardless** of CPRA or ABDR mismatch level
- Programs qualify if they have transplanted at least **4** pancreata from donor hospitals **>250NM** from the transplant program in the previous 2

Summary of discussion:

The Committee reviewed previous recommendations and finalized new ones for facilitated pancreas allocation changes, to be developed ultimately with continuous distribution policy. The recommendations are as follows:

- OPOs and the OPTN are permitted to make FP offers if no pancreas offer has been accepted **five hours** prior to the scheduled donor organ recovery
- Apply facilitated pancreas bypasses to candidates registered at transplant hospitals > **250NM** from the donor hospital
- Apply bypasses to **kidney-pancreas (KP) and pancreas** candidates

- Bypass all candidates at non-facilitated programs, **except for** >80% CPRA or 0ABDR mismatch candidates
- Programs qualify if they have transplanted at least **2** pancreata from donor hospitals **>250NM** from the transplant program in the previous 2 years

The Committee reviewed current policy as well as previous recommendations along with new insights from the 2022-2024 transplant data. Data from 2022–2024 and prior public comments indicated that increasing the threshold to four transplants lacked support. Members agreed that maintaining the current policy of 2 pancreata transplanted from 250NM or greater away was prudent, as changes could face public resistance and were not substantiated by the data.[1]

Members then discussed the recommendation of bypassing candidates with high calculated panel reactive antibodies (CPRA) or significant ABDR mismatches at non-facilitated programs. The Chair offered that these candidates should not be bypassed as in previous discussions it was highlighted the numbers are small enough and it would not be statistically significant to bypass these candidates. The Committee affirmed this decision, aligning with prior discussions. Members agreed that the number of affected individuals is small and that bypassing them could have unintended consequences for these highly sensitized patients.

The regulatory status of islets also came up during the meeting. A representative from HRSA clarified that while the FDA regulates islets, the OPTN's role is limited to their allocation and matching. Given the complexity of the regulatory landscape, the Committee decided to exclude islets from the facilitated pancreas discussion entirely. This decision was broadly supported to avoid unnecessary complications and maintain focus on pancreas-specific policies.

Ultimately, the Committee finalized its recommendations:

- OPOs and the OPTN are permitted to make FP offers if no pancreas offer has been accepted **five hours** prior to the scheduled donor organ recovery
- Apply facilitated pancreas bypasses to candidates registered at transplant hospitals > **250NM** from the donor hospital
- Apply bypasses to **kidney-pancreas (KP) and pancreas** candidates
- Bypass all candidates at non-facilitated programs, **except for** >80% CPRA or 0ABDR mismatch candidates
- Programs qualify if they have transplanted at least **2** pancreata from donor hospitals **>250NM** from the transplant program in the previous 2 years

To ensure clarity, the public comment process will clearly delineate which elements of the policy remain unchanged and which represent new proposals. The updated language will also provide specific definitions, such as defining "high CPRA" as 80% or greater, to avoid ambiguity.

Next steps:

The recommendations will be documented and will be reviewed again once continuous distribution policy is more clearly developed and refined. Additionally, the Committee emphasized the importance of engaging stakeholders through public comment to validate these recommendations.

[1] OPTN Policy 11.6.A https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf

2. Discussion: Winter 2025 Public Comment

The Committee reviewed decisions made for medical urgency criteria from the in-person meeting and decided upon questions to ask the community to illicit feedback.

Summary of discussion:

No decisions made.

The Committee reviewed the guidelines proposed during the in-person meeting, with members reiterating that though they are seeking feedback on all the criteria for public comment, the update should remove language such as "primary" or "major" criteria to avoid any confusion. Members affirmed that three criteria are clear and would be considered for automatic medical urgency priority approval: a HypoA-Q IA subscore of 12 or greater, CGM (Continuous Glucose Monitoring) data with time in range percentages, and current OPTN policy for Kidney medical urgency criteria. The second set of criteria included additional items under consideration—diabetic ketoacidosis (DKA), cardiac autonomic neuropathy, 1 severe hypoglycemic event in the past 6 months, and exocrine insufficiency—that the committee would like public feedback on.

A significant part of the discussion focused on the need to clarify certain terms in the criteria. For example, the phrase "severe hypoglycemic event" was deemed too vague. Suggestions were made to define this more concretely by including examples like EMS calls or glucagon administration. The term "recorded" was also flagged as potentially restrictive, as it might exclude relevant events that weren't formally documented. Members recommended using a more inclusive term like "documented."

A member brought up their concern with potential challenges associated with CGM data. They highlighted that while programs with endocrinologists can readily access and interpret CGM reports, many patients in underserved regions—particularly in the Southeast—lack access to endocrinologists. Despite this disparity, other members noted that most pancreas transplant programs manage smaller waitlists, which would keep the overall documentation burden manageable. It was indicated that, with experience, staff could learn to streamline data collection processes.

Members also emphasized the importance of making the documentation requirements both reasonable and acceptable for transplant programs. The Vice Chair highlighted that the complexity seen in kidney allocation should not be replicated in pancreas programs. Instead, the process should remain straightforward to ensure feasibility.

To guide public feedback effectively, the committee refined the questions for the community. These included:

- Will the proposed criteria for identification of medically urgent patients ensure appropriate application of medical urgency to candidates?
- Does the proposed criteria provide a clear outline and path for transplant programs and the future review board to apply medical urgency criteria to pancreas candidates?
- Will the proposed documentation burden be acceptable and reasonable for transplant program staff to submit?

Members indicated these questions should aim to ensure the community can indicate whether the right patients are being identified by the medical urgency criteria, and whether the review boards are being supplied with the appropriate tools to apply medical urgency. Members agreed that the questions as revised above will elicit the needed feedback.

Next steps:

OPTN Contractor staff will ensure the updated community questions are included in the public comment update.

3. Graft Failure Next Steps

The Committee reviewed graft failure discussion from in-person and potential project next steps.

Summary of discussion:

No decisions made.

The Committee revisited the data presented during the in-person and agreed that the high rates of missing/incomplete data are hampering the efficacy of the pancreas graft failure definition.

OMB Approval and Operational Planning:
The Vice Chair asked about the timing of the Office of Management and Budget (OMB) approval, which is required before implementing any changes. OPTN Contractor staff clarified that while policy can be developed to change the graft failure definition, such as enhancing data collection, implementation of these changes cannot proceed until OMB approval is secured. The Vice Chair suggested proactive engagement with OMB to avoid delays, but it was noted that OMB operates independently of OPTN. The OPTN Data Advisory Committee (DAC) will guide the process and provide insight on timelines. Staff indicated plans to meet with DAC support staff to address potential concerns early. The project will be presented to DAC beginning of 2025, followed by updates to leadership and the full committee.

Members agreed on the two components of the project, a holistic data review of the Transplant Recipient Registration (TRR) and the Transplant Recipient Follow-Up (TRF) forms, and revision of form response options to no longer include “unknown” or “not done” for example.

Both components require DAC approval, with additional OPTN Policy Oversight Committee (POC) approval needed for the data review. The Committee also plans to involve various stakeholders—such as transplant coordinators, administrators, and the OPTN Operations and Safety Committee (OSC)—in the holistic review process.

The Committee reaffirmed the importance of addressing graft failure comprehensively and committed to ensuring the necessary steps are taken to streamline data collection and improve outcomes.

Next steps:

The OPTN Contractor staff will further develop the project and get it ready to present to DAC in January/February 2025.

Upcoming Meetings

- November 25, 2024

Attendance

- **Committee Members**
  - Asif Sharfuddin
  - Colleen Jay
  - David Lee
  - Jason Morton
  - Mallory Boomsma
  - Muhammad Yaqub
  - Neeraj Singh
  - Oyedolamu Olaitan
  - Stephanie Arocho
  - Todd Pesavento
  - Ty Dunn
- **HRSA Representatives**
  - Marilyn Levi
- **SRTR Representatives**
  - Bryn Thompson
  - Jon Miller
- **UNOS Staff**
  - Stryker-Ann Vosteen
  - Dzhuliyana Handarova
  - Cole Fox
  - Kristina Hogan
  - Houlder Hudgins
  - Lauren Motley